



[BILLING CODE 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed collection, 60-day comment request: Certificate of Confidentiality Electronic Application System

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, to provide the opportunity for public comment on proposed data collection projects, the Office of Extramural Research (OER) of the National Institutes of Health (NIH) is developing an electronic application form for the submission of requests to NIH for Certificates of Confidentiality (CoCs).

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection

techniques or other forms of information technology.

TO SUBMIT COMMENTS AND FOR FURTHER INFORMATION: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dr. Ann M. Hardy, NIH Extramural Human Research Protections Officer and Coordinator, Certificates of Confidentiality, Office of Extramural Programs, OER, NIH, 3701 Rockledge Drive, Room 3002, Bethesda, MD 20892; or call the non-toll-free number (301) 435-2690; or e-mail your request, including your address, to hardyan@od.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

COMMENT DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

PROPOSED COLLECTION: Certificate of Confidentiality Electronic Application System 0925-New, Office of Extramural Research (OER), National Institutes of Health (NIH).

Need and Use of Information Collection: This application system will provide one electronic form to be used by all research organizations that wish to request a Certificate of Confidentiality (CoC) from NIH. As described in the authorizing legislation (Section 301(d) of the Public Health Service Act, 42 U.S.C. §241(d)), CoCs

are issued by the agencies of the Department of Health and Human Services (HHS), including NIH, to authorize researchers conducting sensitive research to protect the privacy of human research subjects by enabling them to refuse to release names and identifying characteristics of subjects to anyone not connected with the research. At the NIH, the issuance of CoCs has been delegated to the individual NIH Institutes and Centers (ICs). The NIH ICs collectively issue approximately 1,000 new CoCs each year for eligible research projects. However, the process for submitting a CoC request is not consistent across the ICs, which creates confusion for applicants. To make the application process consistent across the entire agency, the OER is proposing to use an electronic application system that will be accessed by research organizations that wish to request a CoC from any NIH IC. Having one system for all CoC applications to NIH will be efficient for both applicants and NIH staff who process these requests. As is currently done, the NIH will use the information in the application to determine eligibility for a CoC and to issue the CoC to the requesting organization.

Office of Management and Budget approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours is 1,500.

Estimated Annualized Burden Hours

Type of Respondents	Number of Respondents	Frequency of Response	Average Time per Response (in hours)	Total Annual Burden Hours
CoC Applicants-Private	400	1	1.5	600
CoC Applicants-State/local	450	1	1.5	675
CoC Applicants-Small business	50	1	1.5	75
CoC Applicants-Federal	100	1	1.5	150

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Principal Deputy Director

National Institutes of Health

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